SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 4561–4580

Adulteration, Section 501 (a) (1), the article consisted in part of a filthy substance; and, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502 (l), the article purported to be and was represented as a drug composed wholly or partly of a kind of penicillin and it was from a batch with respect to which a certificate issued pursuant to Section 507 was not effective; and, Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

4561. Sodium ascorbate injection. (F. D. C. No. 37011. S. Nos. 90–433/4 L.)

QUANTITY: 299 25-ampul cartons, 10 6-ampul cartons, and 497 individual ampuls at Kansas City, Mo., in possession of B. F. Ascher & Co., Inc.

SHIPPED: Between 11–28–52 and 6–1–54, a number of unlabeled ampuls in bulk were shipped from Decatur, Ill., and Seymour, Ind.

LABEL IN PART: (Carton) "10 cc. Sodium Ascorbate Injection * * * 10 cc. contain: Sodium Ascorbate equivalent to Ascorbic Acid 1 Gram [or "2 Grams"] * * * For Intramuscular or Intravenous Injection Manufactured for B. F. Ascher & Company, Inc."

ACCOMPANYING LABELING: Pamphlets designated "physician's report."

RESULTS OF INVESTIGATION: After receipt of the article at Kansas City, it was labeled as described above by the consignee, B. F. Ascher & Co., Inc. The above-mentioned pamphlets were printed locally for the consignee.

LIBELED: 7–16–54, W. Dist. Mo.

CHARGE: 502 (a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was effective for the treatment of poliomyelitis, mumps, herpes Zoster, chickenpox, influenza, virus pneumonia, and virus encephalitis; for the prevention and treatment of

measles; and for the prevention of recurrence of herpes simplex; and, 505 (a)—the article was a new drug since it was not generally recognized among qualified experts as safe for use in the treatment and prevention of the above-mentioned conditions, and that as a new drug it could not be lawfully introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 8–19–54. Consent—destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

4562. Procaine penicillin G in aqueous suspension. (F. D. C. No. 36894. S. No. 76–703 L.)

QUANTITY: 108 100-carton boxes and 90 loose cartons at Canton, Mass.

SHIPPED: 10–2–53 and 10–5–53, from Terre Haute, Ind.

LIBELED: 7–13–54, Dist. Mass.

CHARGE: 502 (l)—while held for sale, the article purported to be and was represented as a drug composed wholly or partly of a kind of penicillin, and it was from a batch with respect to which a certificate issued pursuant to the law was not effective since the effective date of the original certificate had expired and an application for an extension of the effective date of the original certificate was denied.

DISPOSITION: 11–26–54. Default—destruction.

DRUG IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4563. Monkey Brand Gland Compound. (F. D. C. No. 36868. S. Nos. 79–316/7 L.)

QUANTITY: 2 drums containing a total of 199,750 tablets in bulk, together with a number of 30-tablet bottles in retail cartons at Columbus, Ohio, in possession of Gold's, Inc.

SHIPPED: The tablets had been shipped in bulk drums on 5–6–52 and 5–17–54, from Baltimore, Md.

LABEL IN PART: (Retail carton) "Now in Tablet Form Original Monkey Brand Gland Compound The Original Gland Tonic * * * Sole Distributors Gold's, Inc. Columbus, O."; (btl.) "Monkey Brand Compound Tablets * * * Contains Vitamin B_1, Iron Carbonate, Nux Vomica, Zinc Phosphide, Cascarin and Damiana."

ACCOMPANYING LABELING: Circulars entitled "Monkey Brand Compound Tablets."

RESULTS OF INVESTIGATION: Upon receipt of the bulk shipments of the tablets, the consignee, Gold's, Inc., repackaged the tablets into bottles and cartons labeled as described above. The bottle labels and cartons, together with the above-mentioned circulars, were obtained by the consignee from local printers.

LIBELED: 6–30–54, S. Dist. Ohio; libel amended on or about 7–21–54.

CHARGE: 502 (a)—the labeling of the article, while it was held for sale, namely, the carton and bottle labels and the above-mentioned circulars, contained false and misleading representations that the article was effective for enriching the blood, toning up the nervous force, revitalizing persons with a tired, worn-out, old age feeling and lack of ambition, and those who suffer from loss of sleep, impaired appetite, and nervousness; restoring sufferers to health,